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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,896	06/11/2001	Rebecca E. Cahoon	BB-1313	2782

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Legal Patents
Wilmington, DE 19898

EXAMINER	
BUI, PHUONG T	
ART UNIT	PAPER NUMBER
1638	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/857,896	Cahoon et al.
Examiner	**Art Unit**
Phuong Bui	1638

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Nov 6, 2002*

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24, 26-28, 30-35, and 37-39* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 26-28, 30-35, and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Amendment B, Paper No. 12, filed November 6, 2002. Applicant elects Group I, claims 24, 26-28, 30-35 and 37-39 (SEQ ID NO:31 encoding SEQ ID NO:32) without traverse. Claims 25, 29 and 36 have been canceled. Claims 24, 26-28, 30-35 and 37-39 are pending and are examined in the instant application. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:31 and its corresponding amino acid sequence SEQ ID NO:32, it is unclear what region of SEQ ID NO:31 encodes SEQ ID NO:32. Clarification is required.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, is attached to the instant Office action.

Drawings

4. The following informality has been noted and requires correction in response to this Office Action. Since each page of the drawings must be numbered separately, i.e. "Figure 1A," "Figure 1B," etc., Applicant is required to amend the Brief Description of the Drawings as well as submit new drawings containing the appropriate figure designations in response to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 24, 26-28, 30-35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is encompassed by "an Mlo homolog polypeptide": 1) is Applicant claiming a polypeptide obtained from an Mlo homolog having no functional recitation? 2) how is a "homolog" defined -- how does "a Mlo homolog" differ from "a Mlo"? 3) is Applicant claiming a polypeptide having "Mlo homolog" activity?; and if so, 4) what does Mlo activity encompass, and 5) how would one skilled in the art determine sequences having 90% to 95% sequence identity with SEQ ID NO:32, or sequences which hybridize to polynucleotides encoding said sequences, and having Mlo homolog activity? While the term "Mlo homolog" may be known in the prior art, a polypeptide having "Mlo homolog" activity is not defined by Applicant's disclosure nor by the prior art. The purpose of 35 USC 112, second paragraph is to allow the public to determine exactly what the boundaries of the claimed invention are. In the instant application, the claims are drawn to sequences encoding polypeptides having 90-95% sequence identity to SEQ ID NO:32, or polynucleotides which hybridize thereto. While the activity of SEQ ID NO:32 may be inherent in a complete protein, sequences encoding polypeptides having x% sequence identity to SEQ ID NO:32, or sequences which hybridizes thereto, and having "Mlo homolog" activity cannot be reasonably apprised by one skilled in the art since it is unclear what the claimed activity involves. In certain instances, the name of a protein also implies its activity, such as "ligase", and thus "a polypeptide having ligase activity" would be clear to one skilled in the art. In the instant application, "Mlo homology polypeptide" does not imply a function, and while "Mlo" or "Mlo homolog" may be

terms of the art, one skilled in the art would not be reasonably apprised of the metes and bounds of having "Mlo homolog" activity. Clarification and/or correction are required.

Claim Rejections - 35 USC § 101 Utility

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 24, 26-28, 30-35 and 37-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility. The claims recite "a Mlo homolog polypeptide". Because it is unclear what function is associated with such recitation, it is unclear what utility the claimed polynucleotide would have based upon said recitation, i.e., would a Mlo homolog have the same activity and function as a Mlo? Additionally, the specification stated that partial or complete inactivation of existing plant Mlo results in increased disease resistance (page 2, first full paragraph). The specification further stated sense and antisense inhibition or targeted gene disruption of Mlo and Mlo-related genes would also increase pathogen resistance (p. 2, second full paragraph). However, the claims recite polynucleotides encoding Mlo homolog polypeptides having 90-100% sequence identity with SEQ ID NO:32, polynucleotides which hybridize thereto under specified hybridization conditions, or the polynucleotide of SEQ ID NO:31. It would appear that Applicant desires protein expression/over-expression of Mlo homolog polypeptides in a host, such as a plant host. In fact, the specification set forth the steps for expressing Mlo homolog polypeptides (p. 14, third full paragraph). However, it is unclear how expressing or introducing additional Mlo homolog

polypeptides in a plant would increase disease resistance or induce a hypersensitive response. Applicant does not teach how protein expression or how the claimed polynucleotides should be used to achieve disease resistance. It is also unclear that over-expressing Mlo homolog polypeptides in a plant would have the opposite effect and result in a more disease-susceptible plant. Applicant should note that the claimed polynucleotides are degenerant DNAs, and thus would not hybridize to a genomic sequence encoding the Mlo homolog polypeptide for sense or antisense inhibition. Applicant should further note that polynucleotides which hybridize to degenerant DNA under specified hybridization conditions would also not hybridize to genomic sequences. Neither Applicant's disclosure nor the prior art teaches using the entire SEQ ID NO:31 polynucleotide sequence for sense or antisense inhibition. The prior art recognizes using much shorter sequences for sense and antisense inhibition. Applicant does not disclose a single utility for the claimed polynucleotides, or how the claimed polynucleotides can be used to achieve disease resistance.

Moreover, the specification stated "Mlo-related cDNA clones and DNA segments of genomic DNA, and their homologs and derivatives, may also be used as molecular probes to track inheritance of corresponding loci in genetic crosses, and thus facilitate the plant breeding process. Moreover, these DNA sequences may also be used as probes to isolate, identify and genetically map Mlo and other closely related disease resistance genes" (p. 2, third full paragraph). However, a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use and therefore is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while pathogen resistance would provide substantial benefit to the public, it is unclear how one of ordinary skill in the art would be able to use the claimed nucleotide sequences of the instant application to achieve the desired pathogen resistance without having to carrying out further research to identify or reasonably confirm a real world context of use. It is also unclear how tracking inheritance of corresponding loci in genetic crosses would be immediately useful to the public. Moreover, it is unlikely that the claimed polynucleotides would be useful as probes to identify and genetically map Mlo and other closely related disease resistance genes because of lack of hybridization of degenerant DNA to genomic DNA and the lack of guidance for using the full-length genomic sequence as a probe as set forth above.

Thus, for the reasons set forth, the claimed sequences do not have a real-world use and hence lack substantial utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claims 24, 26-28, 30-35 and 37-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or

a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 24, 26, 30-35 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims reciting 90-95% sequence identity and hybridization language lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass Mlo homologs from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and other Mlo homologs, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

9. No claim is allowed. The claims are free of the prior art.

10. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
January 20, 2003

PHUONG T. BUI
PRIMARY EXAMINER